STATUS OF THE CLAIMS

Claims 2, 6, 10, 15-21, 24 and 28-29 were pending in this application.

Claims 2, 6, 10, 15-21, 24 and 28-29 remain finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Yiv et al., U.S. Patent 6,245,349 in view of Weder WO 96/37192.

Claim 10 has been cancelled.

Claims 2, 6, 15-21, 24 and 28-29 are presented for reconsideration.

REMARKS

Applicants propose to amend their claims in order to more particularly point out and distinctly claim their invention. Thus, independent claims 28 and 28 now recite a "highly homogeneous nanodispersion having a Gaussian distribution" as disclosed at page 2, 5th full paragraph and in the paragraph bridging pages 7-8. Also the limits of claim 10 regarding component (b) have been incorporated in part into independent claims 28 and 28. Since claim 10 fails to further limit amended claim 28, it has been presently cancelled. Additionally claim 18 was amended to delete overlap of Markush group members. Since no new matter has been added and the scope has been narrowed, entry of this amendment is respectfully solicited.

Claims 2, 6, 10, 15-21, 24 and 28-29 remain finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Yiv et al., U.S. Patent 6,245,349 in view of Weder WO 96/37192.

The examiner asserts that Yiv uses methods of preparing nanodispersions that do not need high shear mixing equipment, pointing to col.8, lines 19ff. The examiner admits that Yiv does not use ethanol but asserts that it is taught. The examiner asserts that WO '192 teaches similar dispersions using ethanol.

Applicants respectfully traverse this rejection for the reasons that follow.

Yiv et al., U.S. Patent 6,245,349, is entitled DRUG DELIVERY COMPOSITIONS SUITABLE FOR INTRAVENOUS INJECTION. Yiv discloses injectable drug delivery compositions comprising

- between 3 and 50 percent by weight of a phospholipid,
- between 3 and 50 percent by weight of a compound selected from the group consisting of propylene glycol and polyethylene glycol having a weight average molecular weight of from 200 to 4000, and mixtures thereof, and
- between 3 and 50 percent by weight of a high HLB surfactant having an HLB value of at least about 12.

As taught at col. 6, lines 6-17:

> The high HLB surfactants useful in the drug delivery compositions generally have an HLB value of at least 12 and more preferably at least about 15. These surfactants are characterized as having predominantly hydrophilic properties. The preferred surfactants are nonionic and are acceptable for the chosen route of administration. Such high HLB surfactants are known to those of skill in the art. Preferred surfactants found useful in the present invention are the C_{20-130} sorbitol and sorbitan monoesters, diesters, and triesters, and polyoxyethylene (POE) derivatives thereof having 1 to 90 POE groups, e.g., polyoxyethylene sorbitan monooleate and sorbitol hexaoleate POE (50).

Tween 80, a polyoxyethylene (20) sorbitan monooleate; HLB = 15, is the only high HLB surfactant employed in any of the working examples. Applicants note that polyethoxylated sorbitan fatty acid esters such as Tween 80 are outside the amended scope.

Weder, WO 96/37192, teaches the therapeutic or cosmetic use of sphingolipids and how to enable the preparation of suitable topical or parenteral dosage forms containing this specific active ingredient. Essential component c) of the claimed compositions is a partial fatty acid ester of polyoxyethylene sorbitan such as Tween 80. See page 26, last line and the discussion starting at page 11, line 1 and ending at page 12, line 3. As mentioned above, polyethoxylated sorbitan fatty acid esters such as Tween 80 are outside the amended scope.

The examiner has stated that using ethanol to form an aqueous dispersion is conventional and dependant on the utility of the formulation. However, the '192, reference does not teach that ethanol is an essential component. On page 19 different pharmaceutical formulations are disclosed which include those that are free of ethanol. Hence the use of ethanol to form an aqueous dispersion is an optional expedient.

In summary, Yiv teaches injectable drug delivery systems comprising propylene glycol and/or polyethylene glycol and high HLB surfactants, in particular polyethoxylated sorbitan fatty acid esters such as Tween 80, as essential components, and Weder teaches drug and cosmetic compositions comprising sphingolipids and polyethoxylated sorbitan fatty acid esters such as Tween 80 as essential components, with ethanol as an optional component. There are multiple differences between the injectable drug delivery systems of Yiv and Weder's drug and cosmetic compositions. Since a proper combination of these references would retain all the essential components, applicants aver that only hindsight would enable one to select certain optional components from one reference and to discard essential components from other, e.g. to discard polyethoxylated sorbitan fatty acid esters such as Tween 80, as is required to reconstruct the present invention. Therefore the combination of these 2 references is improper *per se*. And even if proper it would not suggest the presently claimed invention for the reasons above.

Reconsideration and withdrawal of the rejection of claims 2, 6, 15-21, 24 and 28-29 under 35 U.S.C. § 103(a) as being unpatentable over Yiv et al., U.S. Patent 6,245,349 in view of Weder WO 96/37192, is respectfully solicited in light of the remarks *supra*.

Since there are no other grounds of objection or rejection, passage of this application to issue with claims 2, 6, 15-21, 24 and 28-29 is earnestly solicited.

Applicants submit that the present application is in condition for allowance. In the event that minor amendments will further prosecution, Applicants request that the examiner contact the undersigned representative.

Respectfully submitted,

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